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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,204	06/22/2001	Moshe Fleshner-Barak	1662/53002	7559

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 08/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/887,204	FLESHNER-BARAK ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-98 and 102-112* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *90-96* is/are allowed.

6)☒ Claim(s) *1-89,97,98 and 102-112* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of Terminal disclaimer filed 04/28/05; amendment and remarks filed 04/04/05. Claims 1-98 and 102-112 are pending.

Response to Amendment

Claims 99-101 are indicated canceled and also contains the text of the claims. A canceled claim may not have to repeat the text of the claim (see MPEP 714 [R-2].

Double Patenting

The nonstatutory double patenting rejection of claims 1-33 and 35-82 over US 6,476,006; the nonstatutory double patenting provisional rejection of claims 1-33 and 35-82 over application 10/420,403 published as US 2003/0203878 and over application 10/196,766 published as US 2003/0158154; and nonstatutory double patenting provisional rejection of claims 1-33 over application 10/026,573 published as US 2002/0147208; all the nonstatutory double patenting rejections are withdrawn in light of the terminal disclaimers filed.

Claim Rejections - 35 USC § 102

1. Claims 1-7, 9-14, 19-31, 35-38, 40-50, 52-82 and 97 remain rejected under 35 U.S.C. 102(e) as being anticipated by Curatolo et al. (US 2002/0006443 A1).

Applicants argue that "contacting gastric fluid" is not a statement of intended use and that the amendment to claim 1 further distinguishes over the Curatolo. Furthermore, (regarding claims 22 and 40 and the claims dependent on these claims) applicants argue that the cellulose derivatives of Curatolo "that might be capable of functioning as superdisintegrants in the instant invention" are concentration enhancing in Curatolo and that mere "recitation of an element in a prior art reference is not necessarily sufficient to anticipate. Rather, that particular element must

function or be capable of functioning in the prior art device or composition." Applicants further state that Curatolo does not teach all the elements of claim 52, Curatolo does not disclose any of the limitations of claim 53, Curatolo does not disclose all the limitations of claim 54 and the claims dependent therefrom; Curatolo does not disclose encapsulated bonded combination of gastric retention vehicle and bonded reservoir as is in claim 67 and the claims dependent therefrom; Curatolo does not suggest or teach all the limitations of claim 78; Curatolo does not describe multilayered dosage form of claim 79.

2. Applicants' arguments filed 04/04/05 have been fully considered but they are not persuasive.

While "contacting gastric fluid" may not be a statement of future intended use, it is clear that applicants intended to test the composition in simulated gastric fluid and because the compositions of the instant claims and of the prior art are the same, the compositions which are same must necessarily have the same function.

Although the cellulose in Curatolo is used as concentration enhancing, it is clear that applicants admit that Curatolo discloses the cellulose derivatives. It is noted that the instant claims are directed to a broad recitation of superdisintegrant without recitation of amounts. Also, dependent claims 12 and 13 define superdisintegrant as cross-linked carboxymethylcellulose sodium and sodium starch glycolate respectively. Croscarmellose sodium is cross-linked carboxymethylcellulose sodium. Curatolo discloses a composition that contains sodium starch glycolate or croscarmellose. Thus it is not just a mere disclosure of derivatives of cellulose but specific disclosure of cellulose derivatives that are the same as the superdisintegrants so recited in applicants claims 11-13. It is known in the art that cross-linked

carboxymethylcellulose (AC-Di-Sol™) is a superdisintegrant (Cartilier et al. US 5,989,589 at column 5, lines 8 and 9). In the *Minnesota Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.* case cited by applicants, it is noted that the finding specifically referred to amounts of the silicone that may serve as a lubricant that prevents the resin from becoming tacky during molding; furthermore, the products identified by *Johnson & Johnson Orthopaedics, Inc.* was demonstrated at trial and each displayed a tacky resin. In the present case, croscarmellose sodium is a known disintegrant/superdisintegrant.

Claim 40 is directed to a dosage form or composition or formulation; the gastric retention vehicle comprises a hydrogel, a superdisintegrant and tannic acid and this particular form, though called a gastric retention vehicle in the claim is disclosed in the prior art.

Thus the claims dependent upon claims 22 and 40 are appropriately rejected under 35 USC 102.

Curatolo discloses multi layered tablet, capsule or particulate composition that comprises hydrogel (paragraph [0114]), active agent, tannic acid ad sodium starch glycolate or croscarmellose and these are the limitations of claims 52 and 53, which is a composition or dosage from or formulation. Same compositions or formulations or dosage forms must have the same function and properties. Thus, claims 52 and 53 and the claims dependent therefrom are properly rejected under 35 USC 102. Curatolo also discloses the limitations of claim 67 and 79 in view of the foregoing discussions.

Claim Rejections - 35 USC § 102

3. Claims 83-85 remain rejected under 35 U.S.C. 102(e) as being anticipated by Wong et al. (US 6,342,249). The rejection of claims 99-101 is withdrawn because the said claims are canceled.

Applicants argue that an aspect of Wong's dosage form would defeat what the inventors of the examined application understand the operational principle of Wong's dosage form to be because the push layer in some aspects of Wong "can be omitted." Applicants then went on to say that Wong does not suggest or teach that the drug layer or push layer should contain tannic acid as required by claims 83-85 and that Wong does not teach all the elements of claim 83 and the claims dependent therefrom.

4. Applicants' arguments filed 04/04/05 have been fully considered but they are not persuasive.

There is no recitation of a push layer in claim 83; there is no recitation that the push layer should contain tannic acid. As per applicants' argument, the **push layer may be omitted**; the "may" term accords some optional element to what may or may not be omitted. Claims 99-101 are not include

5. Claims 102-104 remain rejected under 35 U.S.C. 102(b) as being anticipated by Swanson et al. (US 4,326,525).

Applicants argue that Swanson does not disclose or suggest all the elements of claims 102-104 because the device of Swanson does not provide sequential, time-separated dosage of methylphenidate and does not disclose that both sequential release be in the patient's stomach.

6. Applicants' arguments filed 04/04/05 have been fully considered but they are not persuasive.

The method of claim 102 administers a dosage form containing two or more doses of methylphenidate to a patient and the prior art administers a dosage form containing methylphenidate and tannic acid. The administration is oral and orally administered dosage form goes through the stomach. No specific dosage form is claimed and the prior art meets the limitations of the claims, the methylphenidate of the prior art would perform the same function as the methylphenidate of the claim 102. The claim does not recite auxiliary agents or amounts/dose of the methylphenidate that would distinguish the claim from the prior art. Same compositions would have the same properties and functions since a composition and its properties cannot be separated.

Claim Rejections - 35 USC § 103

7. Claims 8,15-18 and 39 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Curatolo et al. (US 2002/0006443).

Applicants argue that the Curatolo does not provide guidance as to how the "particular combination of cellulose derivatives" would produce the particular desired swelling rate that applicants first discovered accrues to the combination recited in claim 8; applicants further state that the person of ordinary skill in the art would not know that a combination of hydroxypropyl methylcellulose and hydroxypropyl cellulose in a ratio of 1:3 and 5:3 would swell and increase the volume of the composition by threefold in about 15 minutes.

8. Applicants' arguments filed 04/04/05 have been fully considered but they are not persuasive.

The difference between Curatolo and claim 8 is the ratio of the celluloses. There is no demonstration that a composition containing the celluloses outside the range limitations of 1:3 and 5:3 would not swell to the degree recited. In the absence of demonstration showing that combination of the celluloses in weight ratios of say 0.5 to 3 to about 5.5 to 3.5 and other ranges outside the recited range would not accord the mixed cellulose to swell three fold, the claimed ratio is not patentable over the prior art disclosing a mixture or blend of hydroxypropyl methylcellulose and hydroxypropyl cellulose.

9. Claims 86-89 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. (US 6,342,249).

Applicants argue that claim 86 is not obvious, and the claims dependent therefrom is not obvious because only porous particles function in the dosage of Wong.

10. Applicants' arguments filed 04/04/05 have been fully considered but they are not persuasive.

Claim 86 does not exclude porous particles. Wong does not teach all the limitations of the claim 86, hence the obviousness rejection. Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the difference is in concentration and unless there is evidence that the recited concentration provides unusual results, the differences in concentration would not support the patentability of subject matter disclosed by the prior art.

11. Claims 22, 34, 35, 97, 98 and 105-112 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. (US 6,342,249) in view of Swanson et al. (US 4,326,525).

Applicants state that neither Wong nor Swanson alone or in combination discloses or suggests all the limitations of the claims because the instant dosage form must degrade into fragments that are too small to cause gastric retention and the prior art does not disclose this aspect.

12. Applicants' arguments filed 04/04/05 have been fully considered but they are not persuasive.

Oral dosage form must necessarily pass through the stomach whether it remains intact en route to the intestine or it undergoes degradation or dissolution or hydrolysis. Wong is deficient in the presence of tannic acid and this deficiency is remedied by Swanson, which discloses a composition comprising tannic acid and methylphenidate. The combination of the two references discloses the composition and the release profile is a function or property of the dosage form. The reservoir contains methylphenidate and methylphenidate composition reads on the reservoir.

Claim Rejections - 35 USC § 112

13. The rejection of claims 88 and 97 under 35 U.S.C. 112, second paragraph, is withdrawn in light of applicants' explanation.

More inventions than 1 are claimed. An effort was made at examining the entire claims in order to expedite prosecution. However, applicants were requested to consider electing a

specific invention for continuation of the prosecution. Applicants were moot on the suggestion. As can be seen bay applicants, examining all the claims was a serous burden.

Claims 90-96 remain allowable.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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